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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/596,915	06/29/2006	Raghupathi Kandarapu	GEN 3.3-008	2317

45776 7590 05/25/2011

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ART UNIT	PAPER NUMBER
1611	

NOTIFICATION DATE	DELIVERY MODE
05/25/2011	ELECTRONIC

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/596,915
Filing Date: June 29, 2006
Appellant(s): KANDARAPU ET AL.

Robert A. Franks
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 03/30/2011 appealing from the Office action mailed 08/30/2010.

(1) Real Party in Interest

The examiner has no comment on the statement, or lack of statement, identifying by name the real party in interest in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The following is a list of claims that are rejected and pending in the application:

Claims 1, 4-8, 12-18, and 21-24 are pending.

Claims 2, 3, 9-11, 19, and 20 are cancelled.

Claims 1, 4-8, 12-18, and 21-24 are rejected.

(4) Status of Amendments After Final

The examiner has no comment on the appellant's statement of the status of amendments after final rejection contained in the brief.

(5) Summary of Claimed Subject Matter

The examiner has no comment on the summary of claimed subject matter contained in the brief.

(6) Grounds of Rejection to be Reviewed on Appeal

The examiner has no comment on the appellant's statement of the grounds of rejection to be reviewed on appeal. Every ground of rejection set forth in the Office action from which the appeal is taken (as modified by any advisory actions) is being

maintained by the examiner except for the grounds of rejection (if any) listed under the subheading "WITHDRAWN REJECTIONS." New grounds of rejection (if any) are provided under the subheading "NEW GROUNDS OF REJECTION."

(7) Claims Appendix

The examiner has no comment on the copy of the appealed claims contained in the Appendix to the appellant's brief.

(8) Evidence Relied Upon

Close et al. European Patent number 0094116 (A2), published Nov. 16, 1983.

4,804,669 LASSEN 2-1989

(9)(a) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1, 4-8, 12-18, and 21-24 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Appellant regards as the invention.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely

exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claims 1, 12, and 18 recite "(b) a subcoating on the core..." and "(c) an acidic functional group containing enteric coating..."and the claims also recite "wherein a subcoating inhibits between active ingredient and an enteric coating" which is the broader statement of the limitation. Specifically, **first**, since a subcoating has already been identified in claims 1, 12, and 18 it is unclear if Appellant is intending to refer to an additional subcoating, or *the* subcoating already identified. For the sake of compact prosecution, the Examiner is interpreting the claim as meaning "the subcoating". **Second**, it appears that a modifier is missing before the phrase "active ingredient". As currently written, it is unclear if Appellant is intending to refer to an additional active ingredient, or *the* active ingredient already identified. For the sake of compact prosecution, the Examiner is interpreting the claim as meaning "the active ingredient". **Third**, since an enteric coating has already been identified in claims 1, 12, and 18 it is unclear if Appellant is intending to refer to an additional enteric coating, or *the* enteric coating already identified. For the sake of compact prosecution, the Examiner is interpreting the claim as meaning "the enteric coating".

Claims 4-8, 13-17, and 21-24 are rejected for depending from at least one of indefinite claims 1, 12, and/or 18.

(10)(a) Response to Argument

Appellant state in the Appeal Brief filed 03/30/2011 that the requirements for definiteness include: "(1) provide clear notice to potential infringers regarding what will constitute infringement; and (2) to provide a clear measure of the invention scope for determining patentability", wherein Appellant believes that "It is apparent that the second function is being served, since the claims were regarded as having sufficiently [sic] clarity to permit the formulation of a final rejection for obviousness. Also, those skilled in the art would certainly be able to assess whether a particular product infringes" (see Appeal Brief, page 10). Appellant's two arguments are not found persuasive. **First**, with regard to the assumption that since an Office Action was able to be formulated that a clear scope of the invention has been set forth, Appellant's argument is not found persuasive. The above 112 second paragraph rejections clearly identify that the instant claim scope is confusing and does not provide clear metes and bounds for the claim. However, for the sake of compact prosecution, the Examiner attempted to interpolate what *may* be the scope intended by Appellant, however, there is insufficient clarity in the claims to identify whether the scope identified by the Examiner for the sake of compact prosecution was the intended scope. **Second**, Appellant merely asserts that "those skilled in the art would certainly be able to assess whether a particular product infringes" (see Appeal Brief, page 10). An unsupported statement declaring what one of skilled in the art would be able to assess is insufficient to overcome a properly set forth rejection based on 35 U.S.C. 112 second paragraph. It is noted that

MPEP 716.01(c)(II) states: "[t]he arguments of counsel cannot take the place of evidence in the record. In re Schulze, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965)".

Appellant further argues that "the articles "a" and "an" are commonly used to refer to one thing or to multiple things" (see Appeal Brief, page 11). Appellant appears to be arguing a different point than that which is of record. Specifically, instant claim 1 recites:

> 1. A solid dosage form comprising:
> (a) a core comprising an acid-sensitive antidepressant active ingredient;
> (b) **a subcoating** upon the core comprising a substance having an amino group that reacts with acid functional groups; and
> (c) an acid functional group-containing enteric coating over **the subcoating**: wherein **a subcoating** inhibits interactions between active ingredient and an enteric coating. (Emphasis Added)

It is unclear from said recitation whether the second "a subcoating" is referring to the original subcoating of (b), or an additional subcoating. For instance, it is clear that "the subcoating" refers to the only previously mentioned subcoating. However, the claim lacks clarity since one can not know whether the second "a subcoating" is the same or different from the first "a subcoating". Appellant further states "it could not possible matter for purposes of determining infringement whether one or more enteric coatings is applied to subcoated cores, since the required function still will be obtained" (see Appeal Brief, page 11). Appellant's argument is not found persuasive since said statement identifies a clear misunderstanding of the weight given in a composition claim to structural limitations. There is a difference between a composition with a single

enteric coating over the entire composition and multiple enteric coatings over the entire composition since a clear structural limitation is required.

Appellant further argues that "Regarding the lack of an article before "active ingredient" in the claims, Appellants submit that this does not render the claims indefinite. Those skilled in the art are aware that pharmaceutical dosage forms sometimes contain more than one drug substance" (see Appeal Brief, page 11). Appellant's argument is not found persuasive. It is noted that Appellant is correct that one of ordinary skill is aware that dosage forms can comprise several drug substances. However, the mere knowledge that a composition can comprise several drug substances does not overcome the grammatical ambiguity that is created by the missing article. Specifically, claim 1 reads:

> 1. A solid dosage form comprising:
> (a) a core comprising **an acid-sensitive antidepressant active ingredient**;
> (b) a subcoating upon the core comprising a substance having an amino group that reacts with acid functional groups; and
> (c) an acid functional group-containing enteric coating over the subcoating: wherein a subcoating inhibits interactions between **active ingredient** and an enteric coating. (Emphasis Added)

One of ordinary skill in the art would have no indication if the second "active ingredient" is the same or different that the first active. Further, basic English grammar requires that an article or some type of modifying term be utilized to distinguish said phrase "active ingredient". This is evidenced within the same claim where Appellant clearly states "**an** acid sensitive antidepressant active ingredient". Appellant states that "Grammatically, it might be better to preface "active ingredient" with "a", and Appellants would consider making this amendment before allowance; however, it is not seen as

affecting the definiteness of the claims" (see Appeal Brief, page 11). Appellant's statement identified a misinterpretation of what would constitute definiteness within said claim. The addition of the term "an" would not render the claim definite since ambiguity would still exist since one would not know if it was the same, or a different active ingredient. The terms "an additional" or "the" may resolve the ambiguity, since they would clearly set forth the metes and bounds with regard to said issue. This is the same issue which exists with the phrases "enteric coating" in the claims. Specifically, claim 1 reads"

> 1. A solid dosage form comprising:
> (a) a core comprising an acid-sensitive antidepressant active ingredient;
> (b) a subcoating upon the core comprising a substance having an amino group that reacts with acid functional groups; and
> (c) an acid functional group-containing **enteric coating** over the subcoating: wherein a subcoating inhibits interactions between active ingredient and **an enteric coating**. (Emphasis Added)

Again, the claim lacks a modifier for the first "enteric coating" and states "an enteric coating" without identifying whether the coating is the same of different from the first coating.

As such, Appellant's arguments are not found persuasive. The claims remain rejected as indefinite.

(9)(b) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1, 4-8, 12-18, and 21-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Close et al (European Patent number 0094116 (A2), published

Nov. 16, 1983) in view of Lassen (U.S. Patent number 4,804,669, Patent issued Feb. 14, 1989).

Close teaches therapeutic, enteric coated granules which comprise a therapeutic active core wherein said core is coated by a first coating, which is subsequently coated with an enteric coating. Said first coating comprises a dispersing aid (see claim 1). Said dispersing aid is taught as being either an alkali metal phosphate or glycine (see claim 8), said glycine is water soluble. Said dispersing aid is present in an amount of approximately 0.5 to 7.5% (see claim 1), with a preferred embodiment being taught in example II being approximately 3.5% of the entire weight of the granules. The active core is taught as being selected from a plurality of active agents, all of which have some sensitivity to acid. It is noted that the first coating of Close would inhibit interaction between the enteric coating and the active since said first coating is located between said enteric coating and said active.

Close fails to directly teach that the active is an antidepressant, as required in claims 1, 12, 18, and 21. Close further fails to teach which specific antidepressant is present, as required in claims 22-24.

Lassen teaches delivery of paroxetine to a human (see Abstract). Lassen teaches that paroxetine has "well-known anti-depressant effects" (see column 1, lines 34-40). Lassen further teaches that it can be useful to enterically coat paroxetine compositions (see column 2, lines 14-28).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize the active of Lassen in the invention of Close. One would

have been motivated to do so since Close is teaching a "superior time release therapeutic" which utilizes an enteric coating (see Close, Abstract), and Lassen is teaching a therapeutic that can be enterically coated. One would further have been motivated to utilize the coating method of Close since Close teaches a dispersing aid which "aid[s] in the dispersing of the enteric coating in the intestines" (see Close, page 5, lines 15-16).

(10)(b) Response to Argument

Appellant argues in the Appeal Brief filed 03/30/2011 that the two assertions by the Office "(1) all of the active ingredients of Close have some sensitivity to acid; and (2) the first coating of Close would inhibit interactions between the enteric coating and the active" are incorrect (see Appeal Brief, page 12). With regard to the first, Appellant states that "all of the active agents disclosed by Close at page 4, lines 3-7 are themselves acidic compounds and would not require any protection against contact with gastric acid" (see Appeal Brief, pages 12 and 13). Appellant's argument is not found persuasive for several reasons. **First**, Close directly teaches the use of enteric coatings, wherein enteric coatings function to protect an active ingredient by not allowing contact with the gastric juices, and thus cannot dissolve in said juices. **Second**, there is a clear nexus between the teachings of Close and Lassen, not only since both are teaching enterically coated actives, but moreover said actives are both directed toward the treatment and alleviation of pain. Therefore, since both of the active ingredients are taught for the same purpose, and are taught as being delivered to the

same environment of use, namely the environment achieved by the use of an enteric coating, the use of one pain relieving active within the enteric coating of another pain relieving composition is *prima facie* obvious. **Third**, Lassen teaches that in column 2, lines 23-25:

> "Tablets may be coated according to methods well known in normal pharmaceutical practice, in particular with an enteric coating."

As such, it is clear that the active ingredient of Lassen is useful in an enteric coating, wherein Close clearly identifies a method of enteric coating which would fall within the category of "normal pharmaceutical practice", given the guidance of Close.

Appellant further argues that the second assertion by the Office, namely, "(2) the first coating of Close would inhibit interactions between the enteric coating and the active", is also incorrect (see Appeal Brief, page 12). Appellant states that combining the teachings of Close and Lassen would result in contact of the active with the enteric coating and would render the composition of Close "at least partially inoperable, and this negates any possible *prima facie* case of obviousness" (see Appeal Brief, page 13). Appellant fails to support said assertion with any evidence. However, the Examiner has set forth a clear *prima facie* case of obviousness supported by the teachings of both Close and Lassen. Namely, Lassen teaches an antidepressant active ingredient, namely, paroxetine, and clearly states that said active ingredient can be coated by any normal pharmaceutical practice, "in particular with an enteric coating", wherein Close clearly identifies a method of enterically coating an active. It is unclear in what way enterically coating an active ingredient which is identified as being able to be enterically coated renders the invention inoperable. Since the Examiner has provided teachings

from the prior art, and clear motivation to combine the references, wherein Appellant has not provided any evidence to rebut the clear finding of *prima facie* obviousness, the rejection of the instant claims as being obvious over Close in view of Lassen is maintained.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Trevor Love/
Examiner AU1611

Conferees:

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